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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,530	07/24/2000	Richard Sackler	200.93185C2C	5659

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EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/624,530	SACKLER ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-10,13-16 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10,13-16 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed January 27, 2005. Claims 6 and 13 have been amended. Claim 24 has been added. Claims 6-10, 13-16 and 20-24 are pending and are examined herein.

Applicant's amendment is sufficient to overcome the 35 USC 102 rejection of claims 6-7, 9 and 13-16 over Paradissis et al. (USPN 5133974) and the 35 USC 103 rejections of claims 8, 10 and 20-23 over Paradissis et al. in the Office Action dated October 04, 2004. Accordingly, the rejections are hereby withdrawn. The following rejections now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8, 13-16, 20-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al. (USPN 4844909).

Goldie et al. teaches a solid release oral dosage form, the dosage form comprising a therapeutically effective amount of hydromorphone (opioid) or salt thereof in a matrix wherein the dissolution rate in vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 mL aqueous buffer at pH 1.6 and 7.2 and at 37 °C overlaps with those as instantly claimed

(Abstract). Peak plasma level is achieved between 2 and 4 hours (Abstract). Therapeutic levels of hydromorphone are maintained in vivo for *at least* 12 hours (col. 2, lines 3-10). Compositions wherein peak plasma levels are achieved between 4 and 8 hours are also taught to provide at least 12 hours of therapeutic effect (col. 2, lines 11-23). Gums, cellulose ethers, acrylic resins, C8-C50 long chain hydrocarbons, fatty acids, fatty alcohols, mineral oils, vegetable oils, waxes and polyalkylene glycols are disclosed as matrix materials (col. 2, line 47-col. 3, line 6). Dosage forms comprising between 2 and 40 mg of hydromorphone are taught (col. 2, lines 41-46). Blood plasma levels are exemplified as 1.0 ng/mL and 2.1 ng/mL at 12 hours and 1.1 ng/mL and 1.4 ng/mL at 24 hours (Tables 5 and 6). Goldie et al. does not specifically disclose a dosage form wherein the peak plasma level is obtained at least 4 to about 8 hours after administration of the dosage form.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a dosage form wherein the peak plasma level is obtained at least 4 to about 8 hours after administration of the dosage form because it is Examiner's position that between 2 and 4 hours includes 4 hours. Accordingly, the scope of Goldie et al. and the instant claims overlap. One would have been motivated prepare a dosage form which achieved maximum plasma levels at 4 hours because of an expectation of similar success in preparing a dosage form which achieved therapeutic effects for at least 12 hours.

Furthermore, even if between 2 and 4 hours is not considered inclusive of 4 hours, it would have been obvious to one of ordinary skill in the art at the time of the

invention to utilize a dosage form with a the peak plasma level obtained at least 4 to about 8 hours after administration of the dosage form because Goldie et al. teaches that dosage forms achieving a peak plasma level between 2 and 4 hours are, surprisingly, interchangeable with dosage forms that achieve peak plasma levels between about 4 and 8 hours after administration. Both dosage forms are taught to achieve the desired effect. Namely, both are taught to achieve a therapeutic effect for at least 12 hours. Accordingly, one would have been motivated to administer a dosage form that achieves a peak plasma level between about 4 and 8 hours after administration because of an expectation of administering a dosage form suitable for achieving a therapeutic effect for at least 12 hours.

It is noted that the exemplified clinical studies teach plasma levels at 24 hours wherein the amount present is a therapeutically effective amount because (1) the dosage form is taught to be therapeutically effective for at least 12 hours and the plasma levels at 24 hours are not significantly different than the plasma levels at 12 hours; and (2) the plasma levels are within the scope of the plasma levels as instantly claimed in claim 20.

Claims 9-10 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al. as applied to claims 6-8, 13-16, 20-21 and 24 above, and further in view of Oshlack et al. (USPN 5286493).

Goldie et al. applies as disclosed above. The reference lacks a specific teaching of the preferred opioids.

Oshlack et al. teaches morphine, hydromorphone and oxycodone as interchangeable analgesics for use in a controlled release dosage form (col. 7, lines 3-37).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the hydromorphone of Goldie et al. with the morphine or oxycodone of Oshlack et al. because (1) Goldie et al. and Oshlack et al. are both directed to controlled release dosage forms; (2) Goldie et al. teaches the use of hydromorphone in the controlled release formulation disclosed therein; and (3) Oshlack et al. teaches hydromorphone, morphine and oxycodone as interchangeable as preferred embodiments of the therapeutically effective agents of the controlled release formulation disclosed therein. One would have been motivated to substitute the hydromorphone of Goldie et al. with the morphine or oxycodone of Oshlack et al. because of an expectation of success in administering of a controlled release dosage form wherein a therapeutic effect of the analgesic agent would be achieved for at least 12 hours, as taught by Goldie et al.

It is noted that it would have been obvious to one of ordinary skill in the art to administer a dosage form with the concentrations as instantly claimed because it would have been obvious to administer a dosage form comprising oxycodone or morphine, generally, and "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments with respect to claims 6-10, 13-16 and 20-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER